

REMARKS

Claims 1-34 are pending in the present application. Claims 1, 13, 20, 22, and 31 are independent claims.

New claims 22-34 are added herein. Claims 23-30 depend from claim 22 and claims 32-34 depend from claim 31. Support for the new claims is found in the specification and drawings and particularly at page 3 lines 11-29; page 4 lines 6-7 and 20-24; and page 5 lines 4-5 and the figures. No new matter is added by virtue of the new claims.

Claim 22 recites a biosensor that comprises "a substrate, a reagent positioned on the substrate, a cover positioned on the substrate, the cover including a top side and a bottom side, the bottom side being coupled to the substrate to define a sealed portion and an unsealed portion, and a non-preformed channel positioned between the unsealed portion and the cover, the channel extending across the reagent.

Claim 31 recites a biosensor that comprises a substrate, a reagent positioned on the substrate, a cover positioned on the substrate, the cover having a top side and a bottom side, and an opening extending between the top and bottom sides, the bottom side being coupled to the substrate to define a sealed portion and an unsealed portion, and a non-preformed channel positioned between the unsealed portion of the bottom side and the cover, the channel extending between the opening and the reagent.

Claims 1-19 are rejected under 35 U.S.C. 112, first paragraph. Independent claims 1 and 13 have each been amended to remove the phrase "lying upon the reagent" as it is not deemed a necessary limitation in light of new amendments to the claims. Claims 2-12 depend from claim 1 and claims 14-19 depend from claim 13. However, it is noted that despite the amendments, the rejection is respectfully traversed. Specifically, it is submitted that adequate support for the phrase "lying upon the reagent" is found in the specification and drawings and particularly in Figures 3 and 5. As such, the amendments to the claims have been made as a matter of preference in describing the claimed invention, and are not meant as a reflection of changes deemed necessary for patentability

purposes. Withdrawal of the rejection leading to allowance of the claims is respectfully requested.

Claims 20 and 21 are rejected under 35 U.S.C. 1112, first paragraph. Claim 20 has been amended to remove the phrase "at least a portion of the thermoset adhesive is positioned on the reagent", as it is not deemed a necessary limitation in light of new amendments to the claims. Claim 21 depends from claim 20. However, it is noted that despite the amendment, the rejection is respectfully traversed. Specifically, it is submitted that adequate support for the phrase "at least a portion of the thermoset adhesive is positioned on the reagent" is found in the specification and drawings and particularly in Figures 3 and 5. As such, the amendment to the claims have been made as a matter of preference in describing the claimed invention, and is not meant as a reflection of changes deemed necessary for patentability purposes. Reconsideration of the rejection, leading to its withdrawal and allowance of the claims is respectfully requested.

Claims 1-3, 9, 10, and 12-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Charlton et al. (US5,759,364). Charlton et al. discloses a sensor 34 made up of an insulating base 36 and an embossed lid 46. (Fig.1).

Claims 1 and 13 have each been amended to state that the bottom surface of its cover is non-embossed. Support for the term "non-embossed" is found in the specification at page 1 lines 17-20, where it teaches that "According to the present invention, a biosensor is provided that forms a capillary channel between a cover and substrate, without the aid of a spacer or the additional manufacturing step of embossing either the cover or the substrate". Additional support is found at page 2 lines 32-34, page 3 lines 3-8, page 12 lines 3-14 as well as Figures 1, 3, 6, and 8. No new matter is added by virtue of the amendment.

In contrast to the present claims, the lid 46 of Charlton et al. is embossed. In this regard, the Examiner's attention is directed to column 3 lines 12-14 and 63-66. With this in mind, it becomes apparent that Charlton et al. fails to disclose or suggest a biosensor that

comprises "a substrate, at least a portion being non-embossed, a reagent positioned on the non-embossed portion of the substrate, and a cover positioned on the substrate, the cover including a top side and a generally flat non-embossed bottom side, the bottom side being coupled to the substrate to define a sealed portion and an unsealed portion, at least a portion of the unsealed portion of the generally flat non-embossed bottom side cooperating with the substrate to define a channel extending across the reagent", as required by amended claim 1. Claims 2-3, 9, 10 and 12 depend from claim 1.

Likewise, Charlton et al. fails to disclose or suggest a biosensor that comprises "a substrate, at least a portion being non-embossed, a reagent positioned on the non-embossed portion of the substrate, and a cover positioned on the substrate, the cover having a top side and a generally flat non-embossed bottom side, and an opening extending between the top and bottom sides, the bottom side being coupled to the substrate to define a sealed portion and an unsealed portion, at least a portion of the unsealed portion of the generally flat non-embossed bottom side cooperating with the substrate to define a channel extending between the opening and the reagent", as recited by amended claim 13. Claims 14-15 depend from amended claim 13.

Claims 1-3, 9, 10 and 12-15 are therefore not anticipated, nor are they disclosed or suggested by the cited reference and are believed to be patentable over Charlton et al. Reconsideration leading to withdrawal of the rejection is respectfully requested.

Claims 1-9, 12, 13 and 16-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Hodges et al. (US 6,174,420). Hodges et al. discloses a cell that includes a spacer sheet (1) with a sample receiving cell (11) within the spacer sheet (1), palladium layers (13, 14) in communication with the cell (11), and notches (16) punched for fluid communication with the cell (11).

To clarify the structure of the claimed biosensor, claim 1 has been amended to recite that cover is positioned on the substrate. Support for the amendment is found in Figures 4-5

where the cover is shown to be positioned on the first surface 22 of the substrate 14. As such, no new matter is added by virtue of the amendment.

The rejection proffers that Hodges et al. discloses "a substrate (bottom element 13 in Figure 15) . . . and a cover (top element 13 in Figure 15)". Paper No. 9, Page 8. In contrast to the structure of the biosensor of claim 1, the palladium layers (13) in Figure 15 are not positioned upon one another. Instead, the layers (13) are spaced apart from one another by the spacer sheet (1).

Therefore, there is no description or suggestion in Hodges et al. of a biosensor that comprises "a substrate, at least a portion being non-embossed, a reagent positioned on the non-embossed portion of the substrate, and a cover positioned on the substrate, the cover including a top side and a generally flat non-embossed bottom side, the bottom side being coupled to the substrate to define a sealed portion and an unsealed portion, at least a portion of the unsealed portion of the generally flat non-embossed bottom side cooperating with the substrate to define a channel extending across the reagent", as required by amended claim 1. Claims 2-9, and 12 depend from amended claim 1.

Likewise, Hodges et al. fails to disclose or suggest a biosensor that comprises "a substrate, at least a portion being non-embossed, a reagent positioned on the non-embossed portion of the substrate, and a cover positioned on the substrate, the cover having a top side and a generally flat non-embossed bottom side, and an opening extending between the top and bottom sides, the bottom side being coupled to the substrate to define a sealed portion and an unsealed portion, at least a portion of the unsealed portion of the generally flat non-embossed bottom side cooperating with the substrate to define a channel extending between the opening and the reagent", as required by amended claim 13. Claims 16-19 depend from claim 13.

Claims 1-9, 12, 13 and 16-19 are therefore not anticipated and are believed to be patentable over Hodges et al. Reconsideration leading to withdrawal of the rejection is respectfully requested.

Claims 1-3, 9, 10 and 12-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Uenoyama et al. (US 6,125,292). Uenoyama et al. discloses a sensor that includes a substrate (4) and a cover film (5). A gap is formed between the cover film (5) and the substrate (4) in the portion other than the edge of the cover film (5). This gap constitutes a capillary passage (1).

As discussed above, claims 1 and 13 have each been amended to state that the bottom side of its cover is non-embossed. In contrast to the present claims, the cover film 5 of Uenoyama et al. is embossed. In this regard, the Examiner's attention is directed to column 4 lines 54-55, where it teaches that the cover film 5 is formed into a predetermined shape and is then placed on the substrate 4.

With this in mind, it becomes apparent that there is no description or suggestion in Uenoyama et al. of a biosensor comprising "a substrate, at least a portion being non-embossed, a reagent positioned on the non-embossed portion of the substrate, and a cover positioned on the substrate, the cover including a top side and a generally flat non-embossed bottom side, the bottom side being coupled to the substrate to define a sealed portion and an unsealed portion, at least a portion of the unsealed portion of the generally flat non-embossed bottom side cooperating with the substrate to define a channel extending across the reagent", as required by amended claim 1. Claims 2-3, 9, 10 and 12 depend from amended claim 1.

Likewise, Uenoyama et al. fails to disclose or suggest a biosensor that comprises "a substrate, at least a portion being non-embossed, a reagent positioned on the non-embossed portion of the substrate, and a cover positioned on the substrate, the cover having a top side and a generally flat non-embossed bottom side, and an opening extending between the top and bottom sides, the bottom side being coupled to the substrate to define a sealed portion and an unsealed portion, at least a portion of the unsealed portion of the generally flat non-embossed bottom side cooperating with the

substrate to define a channel extending between the opening and the reagent", as required by amended claim 13. Claims 14 and 15 depend from claim 13.

Claims 1-3, 9, 10 and 12-15 are therefore not anticipated and are believed to be patentable over Uenoyama et al. Reconsideration leading to withdrawal of the rejection is respectfully requested.

Claims 1 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bhullar et al. (US 6,319,719 B1). Bhullar et al. discloses a capillary hematocrit separation structure that includes a body (12) and a cover (14). See Fig. 1. A reaction region (20) is formed in the body (12) and includes a vent (21). See, Column 3 lines 51-55.

As discussed above, claim 1 has been amended to recite that at least a portion of the substrate is non-embossed and that the reagent is positioned on the non-embossed portion of the substrate.

It is respectfully submitted that Bhullar et al. cannot be said to provide suggestion or motivation to be modified to meet the requirements of amended claim 1. Bhullar et al. teaches away from the claimed invention in that it discloses an embossed body (12) having a reaction region (20) formed in the body (12), which contains a dry reagent. As such, Bhullar provides no motivation or suggestion of a biosensor that comprises "a substrate, at least a portion being non-embossed, a reagent positioned on the non-embossed portion of the substrate, and a cover positioned on the substrate, the cover including a top side and a generally flat non-embossed bottom side, the bottom side being coupled to the substrate to define a sealed portion and an unsealed portion, at least a portion of the unsealed portion of the generally flat non-embossed bottom side cooperating with the substrate to define a channel extending across the reagent", as required by amended claim 1. Claims 9-11 depend from amended claim 1.

It is respectfully contended that the differences between the claimed invention and the cited art are such that Applicants' invention as a whole would not have been obvious to one of ordinary skill in the art at the time the invention was made. It is respectfully contended that the claimed invention meets the test of patentability under 35 U.S.C. 103(a). Entry of the amendments leading to reconsideration of the rejection and allowance of the claims is respectfully requested.

Claims 1 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bhullar et al. (US 6,319,19 B1).

As discussed above, claim 1 has been amended to recite that at least a portion of the substrate is non-embossed and that the reagent is positioned on the non-embossed portion of the substrate. Bhullar et al. teaches away from the claimed invention in that it discloses an embossed body (12) having a reaction region (20) formed in the body (12), which contains a dry reagent.

As such, there is no description or suggestion in Bhullar et al. to one skilled in the art to modify that reference to meet the limitations of amended claim 1. Claims 9-11 depend from amended claim 1.

It is respectfully contended that the differences between the claimed invention and the cited art are such that Applicants' invention as a whole would not have been obvious to one of ordinary skill in the art at the time the invention was made. It is respectfully contended that the claimed invention meets the test of patentability under 35 U.S.C. 103(a). Reconsideration of the rejection and allowance of the claims is respectfully requested.

Claims 2, 3, 7, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bhullar et al. (US 6,319,719 B1) as applied to claims 1 and 9-11 above, in view of Uenoyama et al. (US 6,125,292) and Bhullar (EP 1098000 A2). Bhullar et al. (US 6,319,719 B1) and Uenoyama et al. have been discussed above with reference to

amended claim 1. Bhullar (EP 1098000 A2) discloses a sensor 36 with a lid 32 that has inside surface 34 that is molded to define a channel 38 therein. See, Fig. 11-12.

Claims 2, 3, and 7 depend from amended claim 1. It is submitted that Bhullar (EP 1098000 A2) fails to cure the inadequacies of Bhullar et al. (US 6,319,719 B1) and Uenoyama et al. The Examiner's attention is directed to Figure 14 Bhullar et al. (US 6,319,719 B1), which illustrates an embossed lid 32. Accordingly, the biosensors of Bhullar et al. (US 6,319,719 B1), Uenoyama et al., and Bhullar (EP 1098000 A2) either alone or in combination with one another fail to disclose or suggest "a substrate, at least a portion being non-embossed, a reagent positioned on the non-embossed portion of the substrate, and a cover positioned on the substrate, the cover including a top side and a generally flat non-embossed bottom side, the bottom side being coupled to the substrate to define a sealed portion and an unsealed portion, at least a portion of the unsealed portion of the generally flat non-embossed bottom side cooperating with the substrate to define a channel extending across the reagent", as required by amended claim 1. Claims 2, 3, and 7 depend from amended claim 1.

Regarding claim 13, it is submitted that Bhullar (EP 1098000 A2) fails to cure the inadequacies of Bhullar et al. (US 6,319,719 B1) and Uenoyama et al. Uenoyama et al. has been discussed above with reference to amended claim 13.

As discussed above, claim 13 has been amended to recite that a least a portion of the substrate is non-embossed and that the reagent is positioned on the non-embossed portion of the substrate.

It is submitted that Bhullar (EP 1098000 A2) discloses an embossed lid, Uenoyama et al. discloses an embossed cover film 5, and Bhullar et al. (US 6,319,719 B1) discloses an embossed body 12. As such, it is respectfully submitted that Bhullar et al. (US 6,319,719 B1) cannot be said to provide suggestion or motivation to be modified to meet the requirements of amended claim 13. Specifically, Bhullar provides no motivation or suggestion of a biosensor that comprises "a substrate, at least a portion being non-

embossed, a reagent positioned on the non-embossed portion of the substrate, and a cover positioned on the substrate, the cover having a top side and a generally flat non-embossed bottom side, and an opening extending between the top and bottom sides, the bottom side being coupled to the substrate to define a sealed portion and an unsealed portion, at least a portion of the unsealed portion of the generally flat non-embossed bottom side cooperating with the substrate to define a channel extending between the opening and the reagent", as required by amended claim 13.

It is respectfully contended that the differences between the claimed invention and the cited art are such that Applicants' invention as a whole would not have been obvious to one of ordinary skill in the art at the time the invention was made. It is respectfully contended that the claimed invention meets the test of patentability under 35 U.S.C. 103(a). Entry of the amendments leading to reconsideration of the rejection and allowance of the claims is respectfully requested.

Claims 1-3 and 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bhullar (EP 1098000 A2).

As discussed above, Bhullar discloses a lid 32 with an embossed side that faces the set of metallic deposits 28. See, for example Figures 11, 12 and 14. In addition, a capillary channel forms between the inside surface of the lid 32 and a portion of the electrode set 28. See, Column 6 lines 15-24. In contrast, both amended claims 1 and 13 require that their covers have a generally flat non-embossed bottom surface, at least a portion of the unsealed portion of the generally flat non-embossed bottom cooperates with the substrate to define a channel extending across the reagent.

As such, there is no description or suggestion in Bhullar to one skilled in the art to modify that reference to meet the limitations of amended claims 1 and 13. Claims 2-3 and 9-12 depend from amended claim 1.

It is respectfully contended that the differences between the claimed invention and the cited art are such that Applicants' invention as a whole would not have been obvious to one of ordinary skill in the art at the time the invention was made. It is respectfully contended that the claimed invention meets the test of patentability under 35 U.S.C. 103(a). Reconsideration of the rejection and allowance of the claims is respectfully requested.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Charlton et al. (US 5,759,364). Charlton et al. has been discussed above with reference to amended claim 1. As discussed above, there is no description or suggestion in Charlton et al. to one skilled in the art to modify that reference to meet the limitations of amended claim 1. Claim 11 depends from amended claim 1.

It is respectfully contended that the differences between the claimed invention and the cited art are such that Applicants' invention as a whole would not have been obvious to one of ordinary skill in the art at the time the invention was made. It is respectfully contended that the claimed invention meets the test of patentability under 35 U.S.C. 103(a). Reconsideration of the rejection and allowance of the claim is respectfully requested.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hodges et al. (US 6,173,420 B1). Hodges et al. has been discussed above with reference to amended claim 1. As discussed above, there is no description or suggestion in Hodges et al. to one skilled in the art to modify that reference to meet the limitations of amended claim 1. Claim 11 depends from amended claim 1.

It is respectfully contended that the differences between the claimed invention and the cited art are such that Applicants' invention as a whole would not have been obvious to one of ordinary skill in the art at the time the invention was made. It is respectfully contended that the claimed invention meets the test of patentability under 35 U.S.C.

103(a). Reconsideration of the rejection and allowance of the claim is respectfully requested.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Uenoyama et al. (US 6,125,292). Uenoyama et al. has been discussed above with reference to amended claim 1. As discussed above, there is no description or suggestion in Uenoyama et al. to one skilled in the art to modify that reference to meet the limitations of amended claim 1. Claim 11 depends from amended claim 1.

It is respectfully contended that the differences between the claimed invention and the cited art are such that Applicants' invention as a whole would not have been obvious to one of ordinary skill in the art at the time the invention was made. It is respectfully contended that the claimed invention meets the test of patentability under 35 U.S.C. 103(a). Reconsideration of the rejection and allowance of the claim is respectfully requested.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bhullar et al. (US 6,319,719 B1) in view of Uenoyama et al. (US 6,125,292) in view of Charlton et al. (US 5,759,364). Bhullar et al., Uenoyama et al. and Charlton et al. have each been discussed above with reference to amended claim 1. As discussed above, there is no description or suggestion in Bhullar et al. to one skilled in the art to modify that reference to meet the limitations of amended claim 1. Uenoyama et al., and Charlton et al. fail to cure the inadequacies of Bhullar et al. Claim 12 depends from amended claim 1.

It is respectfully contended that the differences between the claimed invention and the cited art are such that Applicants' invention as a whole would not have been obvious to one of ordinary skill in the art at the time the invention was made. It is respectfully contended that the claimed invention meets the test of patentability under 35 U.S.C. 103(a). Reconsideration of the rejection and allowance of the claim is respectfully requested.

The claims are believed to be in condition for allowance, and allowance of the application is respectfully requested. It is requested that this paper be considered a Petition for Extension of time sufficient to effect a timely response, and that all fees due be charged to Deposit Account Number 02-2958 with reference to (RDID 0030 US).

Respectfully submitted,

The Law Office of Jill L. Woodburn, L.L.C.

Sept. 18, 2003
(Date)

Jill L. Woodburn
Jill L. Woodburn
Registration No. 39,874

128 Shore Dr.
Ogden Dunes, IN 46368-1015
Telephone: 219-764-4005
Fax: 219-764-4070